REMARKS

The Official Action dated February 10, 2004 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claims 34, 44 and 68 are amended to further clarify the lack of "additional sealing means" in the claimed devices and methods. Claims 36 and 44 are amended to correct grammatical errors. It is believed that these changes do not involve any introduction of new matter and do not raise any new issues subsequent to final rejection, whereby entry is believed to be in order and is respectfully requested.

The Examiner has withdrawn claims 40, 51-54, 58, 59 and 72 as directed to non-elected species. Upon allowance of the generic claims from which these claims depend, reconsideration and allowance of claims 40, 51-54, 58, 59 and 72 is respectfully requested.

Claims 33, 44-50, 55-57 and 60-71 were rejected under 35 U.S.C. §102(e) as being anticipated by the Tahi et al U.S. Patent No. 6,358,279. Claims 34-39 were rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103 as unpatentable over Tahi et al. Finally, claims 41-43 and 73-75 were rejected 35 U.S.C. §103 as unpatentable over Tahi et al and further in view of the Werblin U.S. Patent No. 6,413,276. In reply to Applicants' previous arguments, the Examiner asserted that Tahi et al disclose that after implantation, the flexible retainer member is removed from the eye.

However, as set forth in detail below, Applicants submit that the methods defined by claims 33-39, 41-43, 68-71 and 73-75 and the sealing devices defined by claims 44-50, 55-57 and 60-67 are neither anticipated by nor rendered obvious over Tahi et al, alone or in combination with Werblin. Accordingly, these rejections are traversed and reconsideration is respectfully requested.

More particularly, as defined by claim 44, the present invention is directed to a sealing device for use in ophthalmic surgery to replace a cataractous and/or presbyopic natural lens. The sealing device comprises a flexible plug part adapted to seal a capsulorhexis of a capsular bag without additional sealing means and to admit an injection device for injecting a lens-forming liquid material through the capsulorhexis without additional sealing means. The plug part has a slightly larger area than the capsulorhexis and is made of a deformable polymer. The sealing device further comprises an anteriorly protruding removable adjusting means connected to the plug part and capable of positioning the plug part to a desired location.

According to claim 34, the invention is further directed to a method of performing visual correction in a patient by replacing the natural lens with a lens implant. The method comprises (a) excising an area of the anterior capsular bag of the eye having a sufficient size to surgically remove the natural lens; (b) locating a sealing device comprising a flexible plug part and removable adjusting means of a size sufficient to cover said excised area with said adjusting means to a position where a peripheral anterior surface of said plug part contacts the inner posterior wall so as to sufficiently cover said excised area without additional sealing means; (c) delivering a lens filling material into the capsular bag by using a delivering means to temporarily displace and/or deform said plug part to admit passage into the capsular bag of said material; (d) before removing the delivery means, introducing lens forming material into the capsular bag to an extent that said material exerts a sufficient pressure on the posterior side of the plug part to seal the excised area without additional sealing means, so said lens material is prevented from being displaced from the capsular bag to the posterior chamber of the eye; and (e) finalizing the lens forming process in the eye.

Finally, according to claim 68, the invention is directed to method of obtaining visual correction subsequent to surgically removing the natural lens. The method comprises

inserting a plug part of a sealing device comprising a plug part without additional sealing means through a capsulorhexis, said plug part being adapted to cover and seal the capsulorhexis from the inside of the capsular bag without additional sealing means; adjusting the location of said plug part with an adjusting means operable from the outside of the capsular bag; delivering a lens-forming material through the capsulorhexis into the capsular bag by using a delivering means and by displacing and/or deforming the plug part to admit the material; and removing the delivering means from the eye, whereby the plug part retains a sealing position without additional sealing means, thereby preventing displacement of the lens-forming liquid material from the capsular bag.

Advantageously according to the invention, the sealing device and methods employ the plug part which is adapted to seal the capsular bag by the pressure of the lens forming material; therefore, no additional sealing means are required. Particularly, parts protruding from the plug which can damage delicate surrounding eye tissue and/or generate unwanted optical side effects, both during and/or subsequent to the visual correction procedures, are avoided.

Tahi et al corresponds with WO 00/49976 discussed at page 2 of the present application. Tahi et al disclose a mini capsulorhexis valve device which comprises a curved flexible discoid flap-valve member 110 and a curved flexible retainer member 112 attached at a fastening point to the valve member. In use, the flexible retainer member 112 is situated exterior to the anterior capsule 114 such that the interior capsule wall 116 is disposed between the discoid flap-valve member 110 and the flexible retainer member 112, as shown in Fig. 4d.

Thus, while Tahi et al require the external retainer member 112 to affix and therefore seal the capsulorhexis with the flap-valve member, Applicants find no teaching or suggestion by Tahi et al of a sealing device as recited in claim 44, particularly having a flexible plug part

adapted to seal a capsulorhexis of a capsular bag without additional sealing means. In fact, the teachings of Tahi et al are inapposite to the device of claim 44. Further, Applicants find no teaching or suggestion by Tahi et al of a method as recited in either claim 34, wherein a lens forming material is introduced into the capsular bag to an extent that said material exerts a sufficient pressure on the posterior side of a flexible plug part of a sealing device to seal the excised area without additional sealing means, or claim 68, wherein a plug part of a sealing device, adapted to cover and seal the capsulorhexis from the inside of the capsular bag without additional sealing means, retains a sealing position without additional sealing means, thereby preventing displacement of the lens-forming liquid material from the capsular bag. To the contrary, as noted above, Tahi et al disclose the use of an external retainer member 112.

Finally, Applicants find no teaching or suggestion by Tahi et al of a method or a sealing device employing a plug having optical correction properties, and, particularly, providing reduction of aberrations in a wavefront passing through the sealing device. Thus, the methods and devices of claims 65 and 66 are further distinguishable from the teachings of Tahi et al.

In the Official Action, the Examiner asserted that after implantation, the flexible retainer member of Tahi et al is removed from the eye, referring to column 9, lines 4-9. The Examiner concluded that this would leave the sealing device of Tahi et al free of any protruding means and leaving the sealing device to be held in place by the fluid pressure within the capsulorhexis. However, Tahi et al disclose that the flexible retainer member is severed from the flexible valve member after both implantation of a mini capsulorhexis valve device and injection therethrough of a capsular filling material (column 9, lines 5-9).

In contrast, according to claim 44, the sealing device comprises a flexible plug part adapted both to seal a capsular axis of a capsular bag without additional sealing means and to

admit an injection device for injecting a lens-forming liquid material through the capsulorhexis without additional sealing means. While the mini capsulorhexis valve of Tahi et al requires the flexible retainer member throughout the surgical process, the present device is adapted to properly function, free of such additional sealing means, throughout the process. As noted above, outwardly protruding sealing members such as the flexible retainer member of Tahi et al can damage delicate surrounding tissue during the visual correction procedures. On the other hand, the sealing device according to the present invention, wherein the plug part is adapted to both seal the capsulorhexis and to admit an injection device for injecting a lens-forming liquid material, without additional sealing means, avoids damage to delicate surrounding eye tissue.

Similarly, in the method of claim 34, step (b) requires locating a sealing device comprising a flexible plug part and a removable adjusting means to cover the excised area with the adjusting means to a position where a peripheral anterior surface of the plug part contacts the inner posterial wall so as to sufficiently cover the excised area without additional sealing means. In step (d), the lens forming material is introduced into the capsular bag to an extent that the material exerts a sufficient pressure on the posterior side of the plug to seal the excised area without additional sealing means. In contrast, the device of Tahi et al requires maintaining the flexible retainer member throughout this procedure.

Further, in the method of claim 68, the sealing device comprising a plug part without additional sealing means is inserted into the capsulorhexis, after which the lens-forming material is delivered into the capsular bag by using a delivery means and by displacing and/or deforming a plug part to admit the material. In contrast, in use of the Tahi et al device, the flexible retaining member is used to maintain the seal of the valve member throughout this process.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q.2d 1949, 1950 (Fed Cir. 1999). Tahi et al fail to teach a sealing device as recited in claim 44, and a method as recited in claim 34 or claim 68. Moreover, the device of Tahi et al does not provide the improvements of the invention, namely, the absence of additional sealing parts, thereby avoiding damage to delicate parts of the eye. Thus, Tahi et al do not disclose each and every element as set forth in the claims, whereby Tahi et al do not anticipate claims 34, 44 or 68, or any of the claims dependent thereon, under 35 U.S.C. §102.

In order to render a claimed invention obvious, the prior art must enable one skilled in the art to make and use the claimed invention, *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 U.S.P.Q.2d 1481, 1489 (Fed. Cir. 1997). In view of the deficiencies in the teachings of Tahi et al, and the failure of Tahi et al to teach or suggest modifying their teachings to provide a sealing device including a plug part adapted to both seal a capsulorhexis of a capsular bag and admit an injection device without additional sealing means, or methods employing sealing devices as defined in claims 34 and 68, Tahi et al do not enable one of ordinary skill in the art to make the sealing device of claim 44 or to practice the methods of claims 34 and 68. Thus, Tahi et al do not render claims 34, 44 and 68, or any of the claims dependent thereon, obvious under 35 U.S.C. §103.

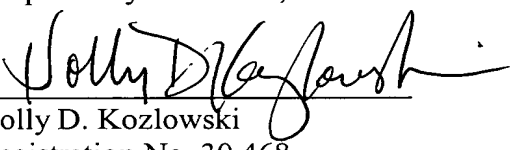
Finally, the deficiencies of Tahi et al are not resolved by Werblin. That is, Werblin is directed to a method of correcting optical aberrations and abnormalities with an optical system having an intraocular lens implant. Applicants find no teaching or suggestion by Werblin relating to correcting an aberration by use of a sealing device, or for modifying the teachings of Tahi et al to provide aberration correction through a sealing device, particularly along the lines of the present invention. Thus, Tahi et al and Werblin are not properly

combinable to place the devices or methods defined by claims 41-43 and 73-75 in the possession of the public. Accordingly, these references do not render the claimed devices or methods obvious under 35 U.S.C. §103.

Accordingly, the methods defined by claims 33-39, 41-43, 68-71 and 73-75 and the sealing devices defined by claims 44-50, 55-57 and 60-67 are neither anticipated by nor rendered obvious over Tahi et al, alone or in combination with Werblin, whereby the rejections under 35 U.S.C. §§102 and 103 have been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§ 102 and 103, and places the present application in condition for allowance. Reconsideration and an early allowance are requested. In the event that the present application is still not in condition for allowance, entry of the present Amendment for purposes of appeal is requested.

Respectfully submitted,



Holly D. Kozlowski
Registration No. 30,468
Dinsmore & Shohl LLP
1900 Chemed Center
255 East Fifth Street
Cincinnati, Ohio 45202
(513) 977-8568

1015387.01